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PCT

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International Bureau



B2

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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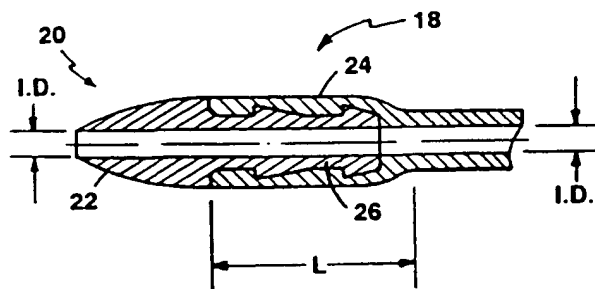
US

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(54) Title: URETERAL STENTS, DRAINAGE TUBES AND THE LIKE



(57) Abstract

This invention is a ureteral stent (10) of a small tubular size, e.g., 6 French, constructed to be used with a guidewire, and including an enlarged entry end (20) and a dissolvable tip member (28) of satisfactory strength and dimension to be secured in the enlarged entry end of the tube. Stents according to the invention incorporate a dissolvable tip of sufficiently large size that the dissolvable tip member can be reliably manufactured and secured to the stent body. The invention also includes medical devices with informational markings (21) formed by application of laser radiation.

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URETERAL STENTS, DRAINAGE TUBES AND THE LIKEField of the Invention

This invention relates to ureteral drainage
5 stents. It also has potential application to other cases
where it may be important to simultaneously realize small
catheter size, special end tip characteristics and
ability to pass over a relatively large guidewire. The
invention also relates to marking medical articles.

10 Background of the Invention

When a patient has an obstruction of the ureter,
it is common to relieve the obstruction with a ureteral
stent to enable urine to pass from the kidney to the
bladder. Typically, the stent extends from the kidney to
15 the bladder. In some cases, the stent has a retention
configuration, such as a pigtail, at its ends in the
kidney and the bladder.

A common case of ureteral obstruction is the
ureteral stone, while cancerous tumor or a feature of the
20 anatomy that allows ureter kinking can also produce
ureteral obstruction.

Another occasion for use of a ureteral stent is
after lithotripsy has been performed to break up a stone.
A stent may be placed to allow fragments of stone to pass
25 from the body and enable the ureter to heal.

Ureteral stents may be introduced to the body
either percutaneously in an antigrade fashion, using, for
example, an adaptation of the Seldinger technique, or
cystoscopically in a retrograde fashion. The stents
30 positioned in the bladder through a cystoscope are passed
into the ureter using direct vision through the endoscope
positioned in the bladder. For thus placing the stent
there are two common methods. One is the so-called over-
the-wire placement method. A guidewire of sufficient
35 stiffness and maneuverability is inserted into the ureter

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It is preferable for the hospital to be able to stock one stent unit to be used in both retrograde placement techniques as it involves less inventory cost. Also a dual-use stent allows the physician to have both
5 options when he opens the package. It is therefore highly desirable that a single stent be capable of both types of placement and capable of using a guidewire as large as the common 0.038 inch guidewire.

It is likewise desirable for a stent to carry
10 markings of its identity so that, for instance, a physician, when withdrawing a used stent, can determine e.g. its length, French size and style, to be able to assuredly select a replacement stent of identical character.

15 Furthermore, it has been found that by using a hydrophilic, dissolving tip on the end of a ureteral stent, significant advantages can be obtained, as are disclosed in U.S. Patent No. 5,049,138, which is hereby incorporated by reference. In this case two very
20 dissimilar materials are employed with two different desirable attributes. The dissolvable tip is very rigid and hydrophilic (lubricious) which both assist in non-traumatic placement. The body of the catheter to reside in the ureter is very soft and pliable for patient
25 comfort and for avoidance of trauma over the duration of its residence in the ureter. By being dissolvable, the hydrophilic entry tip disappears after it has been useful in the placement of the softer material in the ureter. The dissolution of the tip provides a larger passage for
30 improved drainage.

In respect of long-term patient comfort, peristaltic action of the ureter constantly occurs, in normal function. This produces forces and sensations associated with attempted expulsion of the stent. To
35 diminish these tendencies and improve patient tolerance,

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Stents according to the invention incorporate a tip of sufficiently large size that the tip can be reliably manufactured and secured to the stent body.

In preferred embodiments, the dissolvable tip is polyvinyl alcohol containing glycerin as a plasticizer. Such a material is high in viscosity and very difficult to mold. The present invention enables meeting the wall thickness constraints for moldability and strength while accommodating a through-hole that enables passage of the .038 inch wire. In this way a sufficient tubular wall thickness in the connection region, e.g., .008 or .010 inch, can be achieved to enable the entry tip member to be reliably molded and secured in a pre-enlarged end of a 6 French catheter of conventional soft material.

In preferred embodiments the stent is constructed by forming an enlarged end on a soft stent tube, inserting a connector shank of the separately formed tip member, and forming the tube material about the shank. Preferably thermo-forming of the tube material is employed for both preforming and post-insertion tasks.

While the invention has been occasioned by the need for an improved small diameter (e.g. 6 French), over-the-conventional-wire (e.g. .038 inch) ureteral stent having a dissolvable tip, it is realized that the present invention has broader potential applicability for realizing two part stents and catheter constructions having severe size constraints in which the entry tip can provide desirable properties different from the main body of the stent or tube.

Brief Description of the Drawing

Fig. 1 is a view of the preferred ureteral stent according to the invention;

Fig. 1a is another view of the stent (rotated 90° out of the page) in Fig. 1; and

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medial line 19 down the spine of the stent, which is used to orient the pigtails. These and other markings 21, e.g. size and manufacturer, may be made by laser scribing techniques, which are discussed in more detail below.

- 5 The dissolving tip placed in the kidney pigtail end of the stent is made of a thermo-plastic material, e.g., polyvinyl alcohol plasticized with glycerin, formed by injection molding, see the above referenced patent for details.
- 10 In manufacture, the end of the 6 French tubing is preformed to accept the tip member by heating a teflon mandrel and pushing it the required distance into the end of the tube, thereby causing the polymer of the tubing to flow and stretch to a larger size in this localized tube
- 15 region. The tube is then allowed to cool and the mandrel is removed, with the tube end holding its enlarged diameter. The shank 26 of the tip member 20 is then inserted with an interference fit into the end of the tubing, while a .041 inch diameter wire mandrel is
- 20 maintained in the bore of the affected region, i.e. in the tip of the stent lumen and the tip member. The united region of the tip member and the stent are then inserted into a heated mold to displace the thermo-plastic material of the stent body into tighter
- 25 engagement around the barbs of the tip member. The part is then cooled, and removed from the mold and the wire mandrel is removed from the stent, allowing the preformed pigtail to reform to its preset shape. The length of the enlarged region of the stent tubular body 11 is
- 30 approximately 5 millimeters.

In more detail, the final molding procedure is accomplished with a mold formed by an aluminum block in which a hole has been drilled, sized appropriately for the outer final diameter of the enlarged tip portion.

- 35 That mold has a tapered lead-in to facilitate placement

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addition enhancing patient comfort by leaving a small stent in place. During placement, because of its hydrophilic nature, and associated lubricity in the presence of urine, the tip is found to slide smoothly
5 through the ureter without causing trauma, despite its enlarged size. Still the main body of the stent, as mentioned, is of the preferred small size, 6 French, of very soft, patient-comfortable material.

In the case of over-the-wire retrograde placement
10 of the stent over the .038 inch wire guide, in the usual way the wire is put up through the ureter, past the obstruction, and then the stent is passed over the wire and pushed from its trailing end past the obstruction with a rigid push catheter or piece of tubing. The rigid
15 and hydrophilic tip tracks nicely over the guidewire. Once the stent is in place, the wire is removed and the pigtails are allowed to reform in both the kidney and the bladder to retain the stent in place for its useful life. The dissolving mechanism of the tip material is strongly
20 activated within minutes after placement and totally dissolves within two hours, just prior to the anesthesia from the procedure wearing off. By the time the anesthesia wears off only a very soft biocompatible polymer tube of the appropriate small size for comfort is
25 left in place, and remains there during the time required. In addition, the stent retains an enlarged entry region in the place where the dissolving tip material previously resided. This enlarged entry can facilitate entry of stone fragments or debris that may be
30 left from the procedure to assist in their capture and excretion. The enlarged end also will facilitate greater flow during the useful life of the stent. The relatively large diameter of the tube end is of no detriment to the patient because it lies within the confines of the

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Furthermore, a primary advantage of this invention is the enablement of placement over the physician-preferred wire size to reduce the risk of ureteral perforation. For instance, when being pushed past an obstruction, in the absence of a wire, the stent tends to veer off course and the soft spongy ureteral tissue can be punctured easily. By use of the guidewire, the present device will track more accurately around the obstruction and through the ureter without such risk of perforation. Indeed even if use of this product were restricted to the over-the-wire mode of introduction, it would have the virtues of the hydrophilic nature of the tip and the attendant ease of placement while achieving a small size of soft stent material, with eventual disappearance of the tip to enhance drainage capability.

In regard to a preferred specific embodiment it is preferable that the nominal bore of the tube and the tip member be the same, of the order of about .044 inch for passing an .038 inch wire. To facilitate placement over that wire one needs such a degree of clearance between the wire and the actual stent itself. In manufacture, the two mating parts will achieve an .044 inch dimension in the large majority of cases. The tolerance direction for the preferred .004 inch tolerance for the bore of the tip member is in the smaller direction to ensure good trackablility of the tip member on the wire and to ensure that the wall thickness of the shank is sufficient for manufacturability (mold filling) and strength. Because of its hydrophilic nature a close-fitting tip member will not drag excessively on the wire, i.e. not as much as a hydrophobic material might. Also, since the length of such close tolerance extends approximately only one centimeter, much less than the total length of the product itself, little drag is experienced due to closer fitting of the tip.

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channel of an endoscope. The endoscope enables the doctor to visualize the stent and its placement. Although rigid endoscopes are commonly employed for stent placement, increasingly in practice, smaller scopes with smaller working channels are preferred because they can be passed further up the ureter for diagnosis. The ability to employ a smaller stent assists in the choice of a smaller endoscope with smaller working channel. The lubricity and relative short length of the relatively large tip member of the present catheter helps it pass through the relatively small channel.

The stent may be part of a kit, which also includes the positioning or pushing catheter, and a guidewire, preferably of .038 inch diameter. Wires of varying stiffness, from rather flexible to super stiff, may be used. For example, a .038 inch, stiff wire with a 3 cm flexible tip may be provided. The wire may be a .038 inch Glidewire® (Boston Scientific Corporation, Watertown, MA), which is hydrophilically coated. The wire may be a .038 inch Lubrigide® wire (Boston Scientific Corporation, Watertown, MA), a stainless steel wire with 3 cm flexible tip and also including a hydrophilic coating. A 5 French ureteral catheter may also be included as part of the kit. The ureteral catheter is a straight piece of tubing 70 cm long, having inch graduations every centimeter to 50 cm and an adjustable luer-lock hub. The catheter is used by the doctor to evaluate and access the ureter prior to stent placement. The wire is placed in the ureter, followed by the ureteral catheter, which is used to diagnose the tract by injecting contrast materials that indicate the location of obstruction.

(We note that in certain circumstances the entry end of a ureteral catheter may likewise be provided with a separately fabricated, entry-facilitating end tip

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additive, preferably bismuth subcarbonate (30% by weight). In another embodiment, the polymer is C-flex™, which includes bismuth oxychloride (30% by weight) and colorants as additives (Concept Polymers, Clearwater, FL). The markings are visible because they are of a different color, usually dark charred color, than the tube material. The markings are also relieved into the surface of the tube. The marked tube is free of toxic byproducts and compatible for use within the body.

10 While the laser burns, oxidizes or otherwise removes the tubing polymer, in some cases, additives within the polymer matrix enhance the marking effect. For example, PVA without additive is clear and is not effectively marked by the laser, while EVA with the above
15 noted radiopacity enhancing additive is white and is found to be effectively marked by the laser described above. Other laser and polymer combinations may be used with other selected additives to enhance the marking effect. For example, C-flex with the oxychloride
20 additive noted above can also be marked with a CO₂ laser.

Marking the stent in this manner is particularly useful since introduction of another material, such as an ink, is avoided. Further, the markings are retained even after the stent has been within the body for an extended
25 period of time, for example the maximum useful life of typically six to eight weeks. On removal of the stent, the doctor can easily determine the size and length of the stent, and its manufacturer, for selecting and restenting the patient, without remeasuring the length of
30 the ureter by fluoroscopy.

These and other embodiments can be constructed within the spirit and scope of the following claims.

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into a restricted body lumen in which a surface of said end portion is comprised of material that in use has low frictional resistance to sliding.

3. The ureteral stent or the like of claim 1 in
5 which said hydrophilic material comprises polyvinyl alcohol and glycerine.

4. The ureteral stent or the like of claim 1 in
the form of a tube constructed to be inserted endwise
into a restricted body lumen and the end portion of said
10 tip member is comprised of material more rigid than the material of said main body of said tube.

5. The ureteral stent or the like of claim 1
wherein said tip member is sized to enable passage of a
guidewire of outer diameter up to and including 0.038
15 inch.

6. The ureteral stent or the like of claim 1,
wherein the main catheter body is formed of thermo-
plastic material and the distal end portion of the main
catheter body is thermo-formed about retention formations
20 on said connector shank.

7. The ureteral stent or the like of claim 1 in
the form of a perforated drainage catheter.

8. The ureteral stent or the like of claim 1
having retention formations for engagement in the bladder
25 and kidney and a length matching the ureteral distance between those organs.

9. In a ureteral stent or the like comprising

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10. The ureteral stent or the like of claim 9 wherein said polymer includes an additive that enhances marking on exposure to radiation.

11. A method of forming a stent comprising
5 providing a tube of nominal dimension having an enlarged end, providing a preformed member having a lubricous outer surface and a connector shank, inserting the connector shank into the enlarged end of the tube and forming the material of the enlarged end around said
10 connector shank in tight, retaining engagement.

12. The method of claim 11 wherein said tube is comprised of thermo-plastic material and after inserting said connector shank into said enlarged end of said tube, thermo-forming the material of said enlarged end of said
15 tube smoothly into intimate engagement with said connector shank.

13. A medical kit for ureteral drainage, comprising:

a medical tube constructed as described in claim
20 1,
a guidewire of selected flexibility sized to pass through said medical tube, and
a pusher catheter, for locating said medical tube in the ureter by pushing said article over said
25 guidewire.

14. The kit of claim 13 wherein said guidewire is 0.038 inch.

15. The kit of claim 13 further including a ureteral catheter used for initial evaluation of the
30 ureter.

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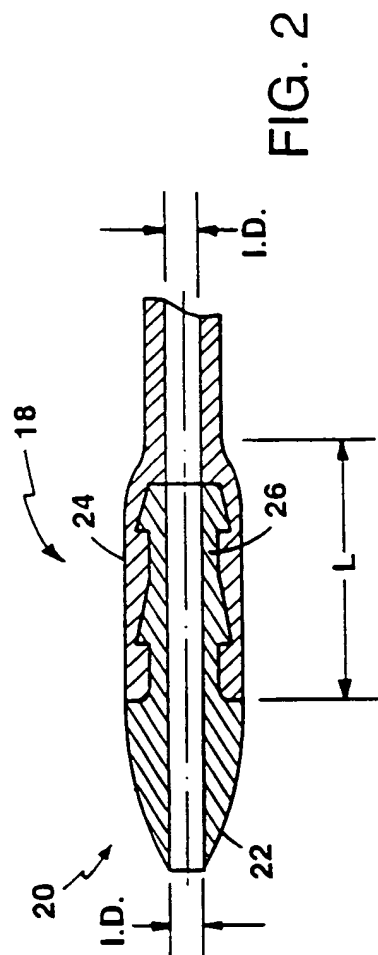


FIG. 2

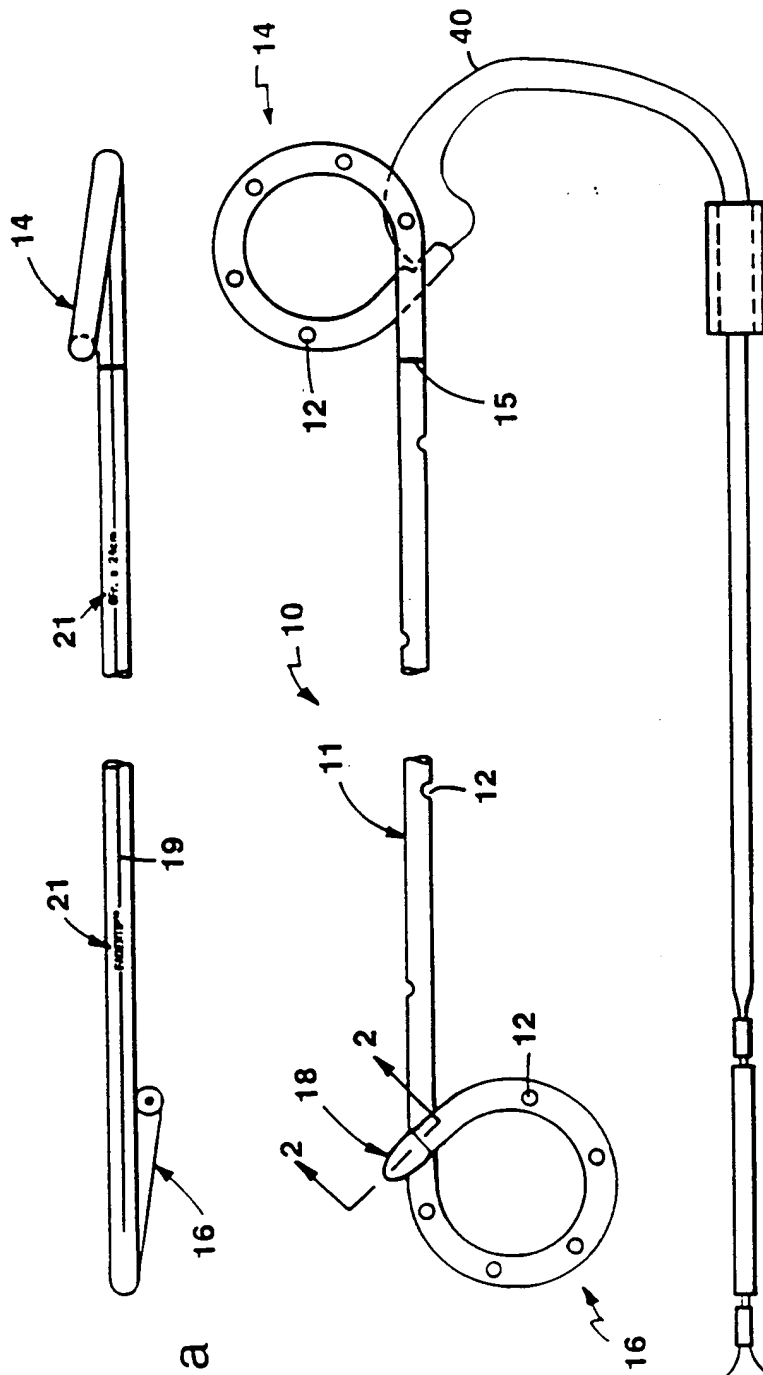


FIG. 1

FIG. 1a

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/04526

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61M 5/32, 25/00

US CL : 604/265

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 264/0.5; 604/52, 53, 93, 109, 164, 171, 172, 264-266, 279, 280; 623/195

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,049,138, (CHEVALIER ET AL.), 17 September 1991. See Fig. 2, column 2 lines 12-18, and column 3 lines 42-49.	1-16
Y	US, A, 5,205,830, (DASSA ET AL.), 27 April 1993. See Fig. 5, entire disclosure, and method of forming an expanded tip disclosed.	1-15
Y	US, A, 5,120,317, (LUTHER), 09 June 1992. See entire disclosure, Fig. 7, and method of forming an expanded tip.	1-15
Y	US, A, 4,212,304, (FINNEY), 15 July 1980. See Fig. 1, and elements 16, 19, 21, and 13. See also kit of Fig. 1 comprising tube (10), pusher catheter (20) and stylet (21) that teaches method of marking device.	8-10, 13-16

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	A*	document member of the same patent family
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Date of the actual completion of the international search

12 JUNE 1994

Date of mailing of the international search report

AUG 03 1994

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REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum)

01194/156W01

Box No. I TITLE OF INVENTION

Ureteral Stents, Drainage Tubes and the Like

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This person is applicant for the purposes of:



all designated States



all designated States except the United States of America



the United States of America only



the States indicated in the Supplemental Box

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☐ applicant and inventor

☒ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

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This person is applicant for the purposes of:



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all designated States except the United States of America



the United States of America only



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☐ applicant and inventor

☒ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

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This person is applicant for the purposes of:



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☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:



agent



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OA OAPI Patent: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Gabon, Guinea, Mali, Mauritania, Niger, Senegal, Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

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JP Japan



KP Democratic People's Republic of Korea



KR Republic of Korea



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LU Luxembourg



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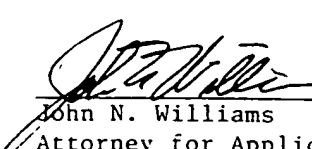
VN Viet Nam

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In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

Box No. VI PRIORITY CLAIM		Further priority claims are indicated in the Supplemental Box <input type="checkbox"/>	
The priority of the following earlier application(s) is hereby claimed:			
Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1) US	(27.04.93) 27 April 1993	08/053,163	
item (2)			
item (3)			
Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required): <input checked="" type="checkbox"/> The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): (1)			
Box No. VII EARLIER SEARCH			
Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request: Country (or regional Office): _____ Date (day/month/year): _____ Number: _____			
Box No. VIII CHECK LIST			
This international application contains the following number of sheets: 1. request : 3 sheets 2. description : 15 sheets 3. claims : 5 sheets 4. abstract : 1 sheet 5. drawings : 1 sheet Total : 25 sheets		This international application is accompanied by the item(s) marked below: 1. <input type="checkbox"/> separate signed power of attorney 2. <input type="checkbox"/> copy of general power of attorney 3. <input type="checkbox"/> statement explaining lack of signature 4. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 5. <input checked="" type="checkbox"/> fee calculation sheet 6. <input type="checkbox"/> separate indications concerning deposited microorganisms 7. <input type="checkbox"/> nucleotide and/or amino acid sequence listing (diskette) 8. <input checked="" type="checkbox"/> other (specify): Transmittal letter	
Figure No. _____ of the drawings (if any) should accompany the abstract when it is published.			
Box No. IX SIGNATURE OF APPLICANT OR AGENT			
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request): BOSTON SCIENTIFIC CORPORATION  John N. Williams Attorney for Applicant			

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1. Date of actual receipt of the purported international application: _____	2. Drawings
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application: _____	<input type="checkbox"/> received
4. Date of timely receipt of the required corrections under PCT Article 11(2): _____	<input type="checkbox"/> not received
5. International Searching Authority specified by the applicant: ISA /	- 6 <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid

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CHAPTER II

DEMAND

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The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only	
Identification of IPEA	Date of receipt of DEMAND
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION	
Applicant's or agent's file reference 01194/156W01	
International application No. PCT/US94/04526	International filing date (day/month/year) (26.04.94) 26 April 1994
(Earliest) Priority date (day/month/year) (27.04.93) 27 April 1993	
Title of invention Ureteral Stents, Drainage Tubes and the Like	
Box No. II APPLICANT(S)	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
Boston Scientific Corporation 480 Pleasant Street Watertown, Massachusetts 02172 United States of America	
Telephone No.:	
Facsimile No.:	
Teleprinter No.:	
State (i.e. country) of nationality: US	State (i.e. country) of residence: US
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
State (i.e. country) of nationality:	State (i.e. country) of residence:
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
State (i.e. country) of nationality:	State (i.e. country) of residence:
<input type="checkbox"/> Further applicants are indicated on a continuation sheet.	

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is ☒ agent ☐ common representative
 and ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.
☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

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 United States of America

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Facsimile No.:

(617) 542-8906

Teleprinter No.:

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV STATEMENT CONCERNING AMENDMENTS

The applicant wishes the International Preliminary Examining Authority*

- (i) ☒ to start the international preliminary examination on the basis of the international application as originally filed.
- (ii) ☐ to take into account the amendments under Article 34 of
- ☐ the description (amendments attached)
 - ☐ the claims (amendments attached)
 - ☐ the drawings (amendments attached)
- (iii) ☐ to take into account any amendments of the claims under Article 19 filed with the International Bureau (a copy is attached).
- (iv) ☐ to disregard any amendments of the claims made under Article 19 and to consider them as reversed.
- (v) ☐ to postpone the start of the international preliminary examination until the expiration of 20 months from the priority date unless that Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

- * Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Box No. V ELECTION OF STATES

The following designated States are hereby elected:

- (i) ☒ all eligible States (i.e., all designated States bound by Chapter II of the PCT).
- (ii) ☐ the States indicated in the Supplemental Box No. V

Box No. VI CHECK LIST

The demand is accompanied by the following documents for the purposes of international preliminary examination:

- | | |
|--|--------|
| 1. amendments under Article 34 | |
| description | sheets |
| claims | sheets |
| drawings | sheets |
| 2. letter accompanying amendments under Article 34 | sheets |
| 3. copy of amendments under Article 19 | sheets |
| 4. copy of statement under Article 19 | sheets |
| 5. other (specify): | sheets |

For International Preliminary Examining Authority use only

received not received

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
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<input type="checkbox"/>	<input type="checkbox"/>

The demand is also accompanied by the item(s) marked below:

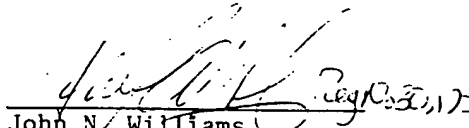
- | | |
|--|--|
| 1. <input type="checkbox"/> separate signed power of attorney | 4. <input checked="" type="checkbox"/> fee calculation sheet |
| 2. <input type="checkbox"/> copy of general power of attorney | 5. <input type="checkbox"/> other (specify): |
| 3. <input type="checkbox"/> statement explaining lack of signature | |

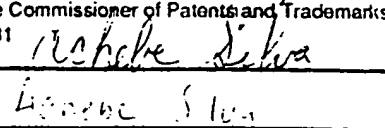
Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand)

*Express Mail *mailing label number TB656845398
Date of Deposit 08 November 1994

I hereby certify that this paper or fee is being deposited with the United States Postal Service *Express Mail Post Office to Addressee *service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231


John N. Williams


Lenore Silva

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date. ☐ The applicant has been informed accordingly.

For International Bureau use only

Demand received from IPEA on:

passes the stent too far up the ureter and needs to pull it down or remove it because of complication in the case. The additional piece of tubing shown half way down the suture is an attachment collar that is attached to hold the suture parallel to prevent tangling prior to use. When the product is removed from the package, the plastic collar is removed and discarded.

As noted above, the stent that has been described is constructed to enable passing through the working channel of an endoscope. The endoscope enables the doctor to visualize the stent and its placement. Although rigid endoscopes are commonly employed for stent placement, increasingly in practice, smaller scopes with smaller working channels are preferred because they can be passed further up the ureter for diagnosis. The ability to employ a smaller stent assists in the choice of a smaller endoscope with smaller working channel. The lubricity and relative short length of the relatively large tip member of the present catheter helps it pass through the relatively small channel.

The stent may be part of a kit, which also includes the positioning or pushing catheter, and a guidewire, preferably of 0.038 inch diameter. Wires of varying stiffness, from rather flexible to super stiff, may be used. For example, a 0.038 inch, stiff wire with a 3 cm flexible tip may be provided. The wire may be a 0.038 inch Glidewire® (Boston Scientific Corporation, Watertown, Mass.), which is hydrophilically coated. The wire may be a 0.038 inch Lubrigide® wire (Boston Scientific Corporation, Watertown, Mass.), a stainless steel wire with 3 cm flexible tip and also including a hydrophilic coating. A 5 French ureteral catheter may also be included as part of the kit. The ureteral catheter is a straight piece of tubing 70 cm long, having inch graduations every centimeter to 50 cm and an adjustable luer-lock hub. The catheter is used by the doctor to evaluate and access the ureter prior to stent placement. The wire is placed in the ureter, followed by the ureteral catheter, which is used to diagnose the tract by injecting contrast materials that indicate the location of obstruction.

(We note that in certain circumstances the entry end of a ureteral catheter may likewise be provided with a separately fabricated, entry-facilitating end tip member of slightly enlarged outer diameter to facilitate the connection, in general manner as described above.)

In some embodiments, the stent can be used with smaller, e.g. 0.025 inch, guidewires, which may be used to position an endoscope which accepts a laser fiber in one working channel and the guidewire in the other working channel. After application of laser energy, the laser and endoscope are removed from the body over the guidewire, leaving the guidewire in the body. The stent can then be positioned over the 0.025 guidewire in a manner similar to that discussed above.

As indicated above, the stent includes markings, such as marking 15 for locating the stent within the ureter and marking 19 down the spine of the stent, which is used to orient the pigtail in the desired direction. These markings, as well as others that indicate the size, length and manufacturer of the stent, can be placed on the stent using a laser scribing system. The system (Model 1750 Universal Laser Systems, Scottsdale, Ariz.) includes a ND-Yag (50 watt, pulse rate 39,949 per cm, pulse width 10 microseconds, pen speed 9 cm/sec) laser and a plotter-positioner that locates the laser energy in accordance with a computer program that may be downloaded from, for example, a CAD system, e.g. AutoCAD® drafting system. The tubing to be used in the

stent, prior to forming retention curls or drainage openings, is placed on the plotter unit using positioning grooves and a mandrel that keeps the tube straight. The laser scribing unit is then driven by the program to laser-write the desired pattern on the tubing. The tubing is then removed from the system and cleaned with a non-reactive solvent (e.g. freon or alcohol) to remove loose residue. In a particular embodiment, the tube (wall thickness 0.015-0.030 inch) is formed of Percuflex polymer (ethylvinyl acetate (EVA)), with a radiopacity enhancing additive, preferably bismuth subcarbonate (30% by weight). In another embodiment, the polymer is C-flex™, which includes bismuth oxychloride (30% by weight) and colorants as additives (Concept Polymers, Clearwater, Fla.). The markings are visible because they are of a different color, usually dark charred color, than the tube material. The markings are also relieved into the surface of the tube. The marked tube is free of toxic byproducts and compatible for use within the body.

While the laser burns, oxidizes or otherwise removes the tubing polymer, in some cases, additives within the polymer matrix enhance the marking effect. For example, PVA without additive is clear and is not effectively marked by the laser, while EVA with the above noted radiopacity enhancing additive is white and is found to be effectively marked by the laser described above. Other laser and polymer combinations may be used with other selected additives to enhance the marking effect. For example, C-flex with the oxychloride additive noted above can also be marked with a CO₂ laser.

Marking the stent in this manner is particularly useful since introduction of another material, such as an ink, is avoided. Further, the markings are retained even after the stent has been within the body for an extended period of time, for example the maximum useful life of typically six to eight weeks. On removal of the stent, the doctor can easily determine the size and length of the stent, and its manufacturer, for selecting and restenting the patient, without remeasuring the length of the ureter by fluoroscopy.

These and other embodiments can be constructed within the spirit and scope of the following claims.

What is claimed is:

1. In a ureteral stent or the like comprising
 - a main catheter body of flexible material having an internal bore of diameter closely corresponding to the outer diameter of a predetermined guidewire with which said main catheter body is constructed to be used, the internal surface of said main catheter body being exposed to directly engage said guidewire,
 - and a tip member at the distal end of said main catheter body, said tip member comprised of hydrophilic material that readily dissolves when contacted with body fluids to which said stent is intended to be exposed and having a through-bore substantially corresponding to the through-bore of said main catheter body,
 - said tip member having two portions, an end portion constructed to serve as the distal end of said stent and an integral connector shank portion smaller in outer diameter than said end portion and constructed to be securely engaged within a distal end portion of the main catheter body,
 - the improvement characterized in that said distal end portion of said main catheter body is larger in outer

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diameter than the general outer diameter of the main catheter body,

said distal end portion of said main catheter body being disposed about and secured to the exterior of said connector shank portion of said tip member, said construction enabling said main catheter body to be of relatively small outer diameter and of thin wall while securely holding said tip member, and, when said tip member is dissolved, providing an enlarged entry to said main catheter body for facilitating entry of fluid and debris.

2. The ureteral stent or the like of claim 1 formed of a radiation-sensitive polymeric material that has been selectively exposed to radiation to produce informational markings.

3. The ureteral stent or the like of claim 1 in the form of a tube constructed to be inserted endwise into a restricted body lumen in which a surface of said end portion is comprised of material that in use has low frictional resistance to sliding.

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4. The ureteral stent or the like of claim 1 in which said hydrophilic material comprises polyvinyl alcohol and glycerine.

5. The ureteral stent or the like of claim 1 in the form of a tube constructed to be inserted endwise into a restricted body lumen and the end portion of said tip member is comprised of material more rigid than the material of said main catheter body.

6. The ureteral stent or the like of claim 1 wherein said tip member is sized to enable passage of a guidewire of outer diameter up to and including 0.038 inch.

7. The ureteral stent or the like of claim 1, wherein the tube is of thermo-plastic material and the distal end portion of said main catheter body is thermo-formed about retention formations on said connector shank.

8. The ureteral stent or the like of claim 1 in the form of a perforated drainage catheter.

9. The ureteral stent or the like of claim 1 in the form of a ureteral stent having retention formations for engagement in the bladder and kidney and a length matching the ureteral distance between those organs.

10. The article of claim 2 wherein said polymer includes an additive that enhances marking on exposure to radiation.

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Europäisches
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Zweigstelle
in Den Haag
Eingangsstelle

European
Patent Office

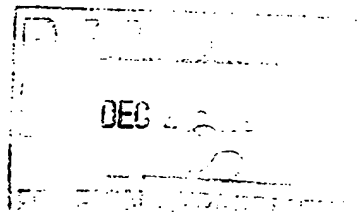
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Département à
La Haye
Section de
Dépôt

WILLIAMS, John, N.
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ETATS-UNIS D'AMERIQUE



Datum/Date

16/12/94

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n°./Patent Nr No./Brevet n°. 94915415.7- -PCT/US9404526
Anmelder/Applicant/Demandeur//Patentinhaber/Propriétaire BOSTON SCIENTIFIC CORPORATION	

1. European patent application No. 94915415.7 has been allotted to the above-mentioned international patent application.
2. FOR ENTRY INTO THE REGIONAL PHASE BEFORE THE EPO the following procedural steps must be taken:
 - 2.1 Within 21 months from the date of filing or (where applicable) from the earliest priority date if the EPO acts as DESIGNATED OFFICE pursuant to Article 22 PCT:
 - a) Filing of a translation of the international application in an EPO official language if the International Bureau did not publish the application in one of those languages (Art. 22(1) PCT and Rule 104b(1)(a) EPC).
 - b) Payment of the national basic fee, the designation fee for each State designated, (where applicable) the claims fees for the eleventh and each subsequent claim and the search fee where a supplementary European search report has to be drawn up (Rule 104b(1)(b), (c) EPC).
 - 2.2 Within 31 months from the date of filing or (where applicable) from the earliest priority date if the EPO acts as ELECTED OFFICE pursuant to Article 39 PCT:
 - a) Filing of a translation as under 2.1 a)
 - b) Payment of the fees as under 2.1 b)
 - c) Filing of the written request for examination and payment of the examination fee (Rule 104b(1)(d) EPC)
 - d) Payment of the renewal fee for the third year, if due before

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the expiration of the 31 month term (Rule 104b(1)(e) EPC).

3. The amounts of the fees (equivalents in all currencies) are regularly published in the Official Journal of the EPO.
4. If the translation of the international application in an official EPO language is not filed in due time, the international application before the EPO is deemed to be withdrawn (Art. 24(1)(iii), Art. 39(2) PCT).
5. The international search report under Article 18 PCT (or the declaration under Article 17(2) a) PCT) was published on 10.11.94.
This publication takes the place of the mention of the publication of the European search report (Article 157(1) EPC).

A request for examination, comprising a written request and payment of the examination fee, must be filed up to the end of six months after the above date. However, in view of Article 22 or 39 PCT in conjunction with Rule 104b(1)(d) EPC, the period for filing the request for examination does not expire before 21 or 31 months respectively from the date of filing (where applicable, the earliest priority date).

If a request for examination is not filed in due time, the European patent application is deemed to be withdrawn (Art. 94(3) EPC).

6. Applicants and/or representatives having their address within the territory of one of the EPC Contracting States are recommended to file EPO Form 1200 (available free of charge from the EPO) when entering the regional phase.
7. Applicants having neither a residence nor their principal place of business within the territory of one of the EPC Contracting States must be represented by a professional representative whose name appears on the EPO list of representatives (Articles 133(2) and 134(1) EPC).

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8. This information letter is addressed by the EPO to the agent, if any, having acted for the applicant during the international phase of the application. Any future notifications on procedural matters will exclusively be addressed to the applicant respectively his European representative, if the appointment of the latter has been communicated to the EPO in due time.
9. For further details see the Supplement No. 1 to Official Journal No. 12/1992 (Information for PCT applicants concerning time limits and procedural steps before the EPO as a designated and as an elected Office under the PCT (as at 01 January 1993)).

RECEIVING SECTION



Anmeldung Nr./Application No./Demande n° //Patent Nr No./Brevet n°

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